

Notice of Allowability

Application No.

09/783,896

Examiner

Joyce Tung

Applicant(s)

GREENE ET AL.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/12/2004.
2. ☒ The allowed claim(s) is/are claims 1, 11, 14-27 (final claims 1-16).
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 8/30/2004
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

REASONS FOR ALLOWANCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/12/2004 has been entered.

This applicant's response filed 7/14/2004 to the Office action has been entered. Claims 1, 11, and 14-27 are pending.

2. The following is an examiner's statement of reasons for allowance:

Concerning claims 1, 15 and 18-21, no prior art has been found teaching or suggesting the method of quantifying molecules expressing a selected epitope in a sample by applying an immuno-RNA amplification in which a fluorescent dye binds to RNA and a quanta of fluorescence signals emitted from stained oligonucleotide is measured, which is directly proportional to epitope detector bound to the surface and molecules expressing the selected epitope in the sample.

Concerning claims 11, 14 and 24-27, no prior art has been found teaching or suggesting the method of detecting molecules expressing a selected epitope in a sample by applying an immuno-RNA amplification in which a second step of reverse transcriptase based reaction or a replicase based reaction is additionally added.

Concerning claims 16-17 and 22-23, no prior art has been found teaching or suggesting the method for quantifying and detecting molecules expressing a selected epitope in a sample by

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applying an immuno-RNA amplification in which the epitope detector is an oligonucleotide attached to a single chain Fv that specifically binds to the selected epitope or an oligonucleotide attached to a constrained epitope specific CDR.

The closest prior art is the references of Eberwine et al. (US 5,922,553, issued July 13, 1999) in view of Sano et al. (US 5,665,539, issued September 9, 1997) and Zeytinoglu et al. (5,874,226, issued February 23, 1999). Eberwine et al. disclose an immuno-RNA amplification for the detection of selected protein (See the Abstract). Sano et al. disclose an immuno-DNA amplification (See column 2, lines 46-52). There is no motivation to combine to render the measuring a quanta of fluorescence signals emitted from stained oligonucleotide, which is directly proportional to epitope detector bound to the surface and molecules expressing the selected epitope in the sample as claimed in claim 1. Zeytinoglu et al. disclose in situ immunodetection of antigens involving polymerase chain reaction (See column 1, lines 36-54). However, there is no disclosure anywhere in Zeytinoglu et al. of doing RNA amplification in combination with reverse transcriptase or replicase reaction. The combination of the teachings of Eberwine et al. and Zeytinoglu et al. do not yield the instant invention as claimed in claim 11. None of the three references disclose the epitope detector is an oligonucleotide attached to a single chain Fv that specifically binds to the selected epitope or an oligonucleotide attached to a constrained epitope specific CDR, which renders the instant invention as claimed in claims 16 and 22.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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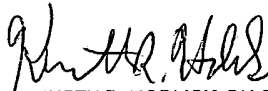
fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 703 (305) 7112. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703 308 1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung JT
October 27, 2004


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
10/28/04